K010910 (1 of 4)

AUG 1 2001

Medicon eG
Traditional 510(k) - HCI

MEDICON eG · POSTFACH 4455 · D-78509 TUTTLINGEN

CHIRURGIE / DENTAL INSTRUMENTE
SURGICAL / DENTAL INSTRUMENTS

MEDICON eG, Chirurgiemechaniker-Genossenschaft
Gänsäcker 15, D-78532 TUTTLINGEN (parcel post)
Postfach 44 55, D-78509 TUTTLINGEN (letter post)
GERMANY

Telefon: (0 74 62) 20 09-0 Telefax: (0 74 62) 20 09-50
Cables: medicon-tuttlingen

e-mail: marketing@medicon.de
sales@medicon.de

homepage: http://www.medicon.de

Ihr Zeichen und Datum Your Ref. and Date	Unsere Zeichen Our Ref.	Telefon-Durchwahl: Direct dialling (phone): (0 74 62) 20 09-	Datum Date

2.

510(k) SUMMMARY
of Safety and Effectiveness
+
SE Comparison Table

Medicon eG
[As required by Section 807.92)]

2.1 **Submitter:** [807.92 (a)(1)]

Medicon eG
Gänsäcker 15 Tel. +49 7462 2009 0
D-78532 Tuttlingen Fax +49 7462 2009 50
Germany eMail sales@medicon.de

marketing@medicon.de

2.2 **Date Summary Prepared:** [807.92 (a)(1)]
March 3, 2001

2.3 Device Names: [807.92(a)(2)]

Proprieatary	MEDICON Yasargil Clip Applying Forceps
Common	Yasargil Aneurysm Clip Applier
Classification	Applier, Aneurysm Clip

2.4. Reason for Submission: [807.81(2)]

New Device

2.5 Predicate Device [807.92(a)(3)]

Manufacturer	Aesculap Inc. K984109
Proprietary Name	Axial Clip Applier
Catalog #`s	FT XXX T
Manufacturer	Aesculap Inc. K940970
Proprietary Name	Yasargil, Caspar, Vario Clip Applier
Catalog #`s	FT XXX T

2.6 Device Describtion [807.92(a)(4)]

There are 15 various Yasargil Clip Applying Forceps with Titanium Jaws. Each Clip Applier is available with two jaw styles; rotatable and rigid.

The shapes, sizes, and materials used are **substantially equivalent** to those of SE devices.

2.7 Intended Use: [807.92 (a)(5)]

The MEDICON Yasargil Clip Applying Forceps are used for holding and applying intracranial aneurysm clips.

The MEDICON Yasargil Clip Applying Forceps are intended for use and handling by professional and qualified surgeons.

2.8 Environment of Use

The MEDICON Yasargil Clip Applying Forceps are intended for use in healthcare facilities, including hospitals, medical clinics and surgical centers.

Within these facilities the MEDICON Yasargil Clip Applying Forceps may be located in areas where sterile surgical/dental instruments are used such as operating rooms for surgery.

2.9 Difference in Design and Technological Characteristics when Compared to SE Devices

[807.92(a)(6)]

Material: Like the SE devices, the MEDICON Yasargil Clip Applying Forceps are manufactured out of stainless steel after ISO 7153-1. The jaws are alloyed with Titanium (TiAl6V4) after DIN ISO 5832-3 and ISO 9713.

Design: The design is very similar. Both MEDICON and SE devices consist of various sizes regarding length, measurement and maximum opening of the jaws.

2.10 Industry Standards: [807.92 (d)]

MEDICON certifies compliance with required ISO/EN/ASTM and other device-related standards that apply to the manufacure, packaging, labeling, sterilization, and reprocessing of subject devices including the validation of these processes.

Substantially Equivalent

2.11 Information Bearing on the Safety and Effectiveness:

[807.92 (b)(3)]

The MEDICON Yasargil Clip Applying Forceps have the same intended use as predicate devices. They are made of identical material. The slight differences in design and size do not adversely affect the safety and effectiveness of this Aneurysm Clip Appliers.

The results of design validation and clinical testing raise no new issues of safety and effectiveness.

2.12 Comparison with predicate devices (table)

	Medicon	Aesculap
INTENDED USE		
The MEDICON Yasargil Clip Applying Forceps are used for holding and applying intracranial aneurysm clips.	YES	YES
METHODS OF STERILIZATION		
Steam Sterilization Processes (DIN 58953-9) : 134° C, 2 bar, induction time at least 5 minutes, or 121° C, 1 bar, induction time at least 15 minutes.	YES	YES
MATERIAL		
Stainless Steel after DIN ISO 7153-1	YES	YES
TiAl6V4 after DIN ISO 5832-3	YES	YES
DESIGN		
Prism Design	YES	YES
Maximum Clip Opening	YES	YES
Identical Material (Clip and Jaw Part of the Applier)	YES	YES
Labeling (Instrument shows Standard or Mini)	YES	YES
Manufactured after F700-93 and ASTM Standard 1B	YES	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Mr. Joachim Schmid
General Manager
Medicon, E.G.
Gaensaecker 15
D-78532
Tuttlingen,
Germany

Re: K010910
Trade/Device Name: Medicon Yasargil Clip Applying Forceps
Regulation Number: 882.4175
Regulatory Class: II
Product Code: HCI
Dated: May 29, 2001
Received: June 15, 2001

Dear Mr. Schmid:

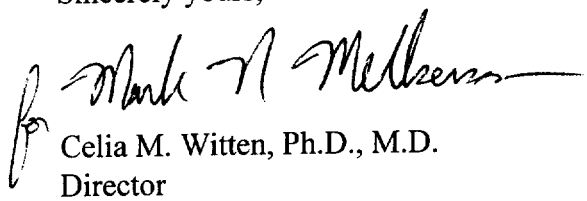
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number	K010910
Device Name	**Medicon Yasargil Clip Applying Forceps**
Classification	**Applier, Aneurysm Clip**
Product Code	**84 HCI** **Class II** **21 CFR 882.4175**

INDICATIONS FOR USE

The MEDICON Clip Applying Forceps are used for holding and applying intracranial aneurysm clips.

The Clips Applying Forceps are intended for use and handling by professional and qualified surgeons.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per CFR 801.109) (Optional Format 1-2-96)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010910